Michael Beck
Cider Production Manager
8614 N. U.S. 27
St. Johns, MI 48879

Dockets Management Branch (HFA-305)
Food and Drug Administration
1240 Parklawn Dr., rm. 1-23
Rockville, MD 20857
Docket No. 99N-1979

To Whom It May Concern:

I would like to urge the FDA to continue to study the alternatives to pasteurization. I feel that pasteurization would take away the ability for people to produce fresh juice. Furthermore, pasteurization equipment is not economically feasible for small producers like myself. Plus, proposed regulations would make it difficult for people that already have pasteurization equipment. I know that research thus far conducted includes: Ultraviolet, Sanitizers, Ultrasound, and Steam Washes. Further research needs to be conducted on validation processes for these methods. Many people feel that the use of Good Manufacturing Process along with Hazard Analysis Critical Control Point program and the use of one the alternative technologies that an adequate microbial control can be achieved.

Our cider mill was one of the first to fresh juice mills to have a GMP's and a HACCP plan. We are also using FDA approved sanitizers for microbial control. During the past two processing seasons we have been studying the effects of sanitizers. Most test have been conducted in our in house lab. I have enclosed a copy of the results of our research. The summary of this research concludes that sanitzers is an effective means of microbial control. However, much research needs to take place. Furthermore, the FDA may want to extend the same deadline on labeling restrictions that orange juice producers received to all juice makers. This is the only fair thing to do.

Thank you,

Michael Beck

Michael Beck

Efficacy of Sanitizing Agents for Pathogen Reduction in Cider Production

Michael J. Beck*

Retail Cider Production Facility, Uncle John's Cider Mill, St. Johns, Michigan

ABSTRACT

The objective of this study was to determine the effectiveness of sanitizers on apple surfaces and its affect on cider. During the autumn of 1997 and 1998, apple and cider samples were assessed for bacterial level. Samples were tested for Total Aerobic Plate Count (TAPC), Coliforms & Escherichia coli (E.coli). Various tests took place involving the facilities in house lab and unpublished tests from Michigan Department of Agriculture (MDA). Samples in 1997 used a chlorine (NaOCl) flume wash followed by a washer/scrubber Chlorine Dioxide (ClO_2) wash. Samples in 1998 used a Peroxyacetic acid flume wash followed by the same ClO_2 wash. 1997 samples used a variety of drop apples; table sorts and tree run fruit. 1998 samples did not include drop apples. Production methods were followed by the plants Quality Assurance program(1).

Key Words: Apples, cider, and sanitizers

A concern over the safety of unpasteurized apple cider has developed after some outbreaks of *E. coli* in 1996(2). Regulations from FDA (3) and local government (4) have come about from the result of these outbreaks. Pasteurization of apple cider is an accepted method of pathogen reduction. However, lower cost alternatives to pasteurization need to be developed because most small producers can not justify the high cost of pasteurization equipment. Furthermore, pasteurization alters the flavor, texture and appearance of cider. Sanitizing agents have shown promise in pathogen reduction. Municipalities have used ClO_2 in potable and wastewater treatment plants for decades, (5) and has been used successfully in the treatment of pathogens on retail package fruit (6).

*Author for correspondence. Uncle Johns, cider production plant, 8614 N. U.S. 27, St. Johns, Michigan 48879. Tel: 517.224.3686 Fax: 517.224.1808; E-mail: cider@ujcidermill.com

Data has shown that hydrogen peroxide solutions have achieved a pathogen reduction in excess of 4-log (7). Washes using NaOCl solutions can provide a 1log reduction in pathogens (8). All of these are economically feasible and practical methods for use in smaller production plants.

MATERIALS AND METHODS

Materials and equipment used were chosen because they were designed for practical use in working environment. In addition, all methods are readily available and economically feasible.

Preparation of aqueous chlorine dioxide. Solutions of ClO_2 were generated on site with a Clo2 generator from CH_20™ International, Olympia Washington. 2 –3 ppm Clo2 was pumped directly into a washer scrubber and applied directly to whole apple surfaces.

Determination of chlorine dioxide concentrations. Titration tests were used to determine ClO_2 ppm in water. Test kits were supplied by the manufacturer and results were recorded daily.

Preparation of aqueous NaOCl solutions. 5.25% sodium hypochlorite was added to flume water to achieve dilutions between 50 – 200ppm. Mean concentrations were 150 ppm.

Determination of NaOCl concentrations. Total Chlorine test strips was used to determine chlorine strength.

Preparation of Peroxyacetic acid solutions. A premixed solution manufactured by ECOLAB Inc., St. Paul MN (Tsunami®) was added to flume water to achieve concentrations up to 80ppm.

Determination of Tsunami® concentrations. Titration tests supplied by the manufacturer were used to determine Tsunami® concentrations.

Testing of whole apples and apple cider. Various methods were used to determine microbial counts. Testing took place in house and occasionally tests were conducted by MDA. No attempt was made to recover damaged cells from low cider pH. Samples of apples were taken before and after sanitizing washes. Cider samples

were taken directly from the bulk tank. Cider samples were tested with Neogens' Hygicult® Series. Plate Count Agar was used for aerobic organisms. Violet Red Bile Agar (VRBA) was used to detect coliform levels. β-Glucuronidase agar (β-GUR) was used to detect generic *E. coli* levels. 100ml samples were taken for tests and allowed to incubate for 24 hours. Sample results would then be recorded in plants haccp plan. Hygicult® tests have a sensitivity of 10^3 CFU/cm^2.

Late in the processing season in 1998, a MethylUmbilliferone glucoronide (MUG) was added to cider sample testing. This test was effective in testing for both coliform and general e-coli. This testing method has a sensitivity of >1 CFU/ cm^2. All in house samples were recorded in the plants haccp plan. Variables vital to test results are also recorded in the plants haccp plan. MDA made several plant inspections during the 1997 and 1998 processing seasons. Their tests included swabs throughout plant and on the food contact surfaces. Samples were also taken on whole apple surfaces and finished product.

RESULTS AND DISCUSSION

Generic *e. coli* was never found in any samples taken in processing seasons 1997 or 1998 All methods of whole fruit washing shows some form of log reduction in organisms (Figure 1 &2). Furthermore, bacteria levels dropped in 1998 due to the change in manufacturing practice of not using windfall apples (Figure 2). Silk et al (9) displayed similar characteristics in another cider study. Hygicult® tests are not a most probable number test and if comparison charts are not used, they can become subjective in their interpretation. Late in processing season 1998, MUG testing was added to cider sampling. MUG tests are a most probable number test. This method of sampling is also more sensitive and can achieve results that are more accurate. Both methods of sampling required 24 hrs. of incubation at 37°C.

MDA testing revealed much about plant sanitation and the quality of apples coming into the plant. Results of these tests would show us where the plant could use improved sanitation. Consequently, bacterial levels were reduced throughout the plant and in the finished product. This could skew the results of sampling slightly. The largest variable in bacterial reduction was the increased contact time of the sanitizers on fruit. When the plant had the ability to slow its process down to close to minimum speeds tests

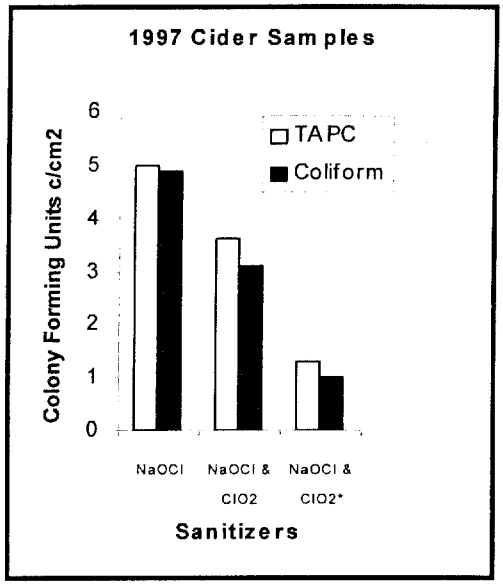

***Figure 1**. 1997 cider sampling results. Cider apples used were a combination of tree run fruit, table sorts, and windfall apples.*
** Test samples when sanitize contact time was increased.*

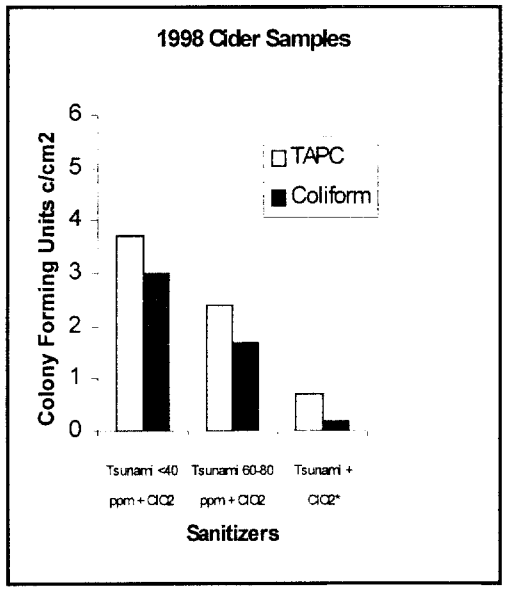

***Figure 2**. 1998 cider sampling results. Cider apples used contained no drop apples.*
** Test samples when sanitizer contact time was increased.*

indicated no form of organisms living in cider. sanitizer levels would affect bacterial kill. (Figure 1 &2). Sanitizer strength would deviate from day to day. However, Chlorine Dioxides standard deviation is signifigantly lower. Metering devices make ClO_2 simple to use.

Because of high flume water solids NaClO strength would drop steadily throughout the day. However, Tsunami® would stay close to same strength consistently under the same conditions. Sanitizers did not off gas odors or cause irritation in use. Although, mixing sanitzers in flume tank did give off unpleasant odors. When mixing proper safety precautions should be followed. Care should taken when priming the Chlorine Dioxide unit for seasonal startup.

The combination of sanitizers and good manufacturing practices can achieve adequate bacterial kill. Furthermore, sanitizers had no effect on cider taste and quality. In addition, a substantial shelf life extension was achieved as a byproduct of sanitizer use. Results of this study substantiates previous findings. Further research needs to focus on validation of these processes so that cider producers may take advantage of them.

ACKNOWLEDGEMENTS

Many thanks to the companies that helped make this research possible. Michigan Orchard Supply, Allegan, MI; CH_20 International, Olympia; WA, Ecolab®, St. Paul, MN. Special thanks to John Tilden, Jerry Wojtala, Doug Park and the Michigan Department of Agriculture for their help and expertise in this project. Plus, many thanks to Bob Tritten and MSU extension for their help.

REFERENCES

1. Uncle Johns Cider Mill. Quality Assurance Plan, 1997 & 1998. St. Johns, MI
2. Centers for Disease Control. 1996 Outbreak of *Escherichia coli* 0157:H7 infections associated with drinking unpasteurized commercial apple juice-British Columbia, Colorado, California, & Washington, October 1996. Morbid. Mortal. Weekly Rep.45:975.
3. Food and Drug Administration. 1998. Pub. No. 98-18287 21 CFR Part 101. U.S. Health and Human Services. Springfield, VA.
4. Michigan Department of Agriculture. 1997 & 1998. Good Manufacturing Practices for Michigan Apple Cider. Food & Dairy Div. Lansing, MI
5. Benarde, M. A, I.S. Bernard, V.P. Olivieri, and M.L. Granstrom. 1965. Efficiency of Chlorine Dioxide as a Bactericide Appl. Microbiol. 13:776-780
6. Roberts, R. G., S. T. Reymond. 1994. Chlorine Dioxide for Reduction of Postharvest Pathogen Inoculum during Handling of Tree Fruits. Applied & Environmental Microbiology. 60 2864-2868
7. Sapers, G. M., R. L. Miller & A. M. Mattrazzo. 1998. Efficacy of Sanitizing Agents in Inactivating *Escherichia coli* in Cider Apples. Plant Sci.\ GMSRJD38.DOC
8. Suslow T. 1998. Postharvest Chlorination. University of California. Publication 8003
9. Silk, T. M., E. T. Ryser, C. W. Donnelly. 1997. Comparison of Methods for Determining Coliform and *Escherichia coli* Levels in Apple cider. J. Food Protection 60: 1302 - 1305

The sender has requested notification upon delivery.
Immediately upon receipt, please telephone:

Name: _____

Tel. No.: ( ) _____

EXPRESS MAIL

UNITED STATES POSTAL SERVICE

www.usps.gov

EXPRESS MAIL
UNITED STATES POSTAL SERVICE™

POST OFFICE TO ADDRESSEE

ORIGIN (POSTAL USE ONLY)			
PO ZIP Code	Day of Delivery ☐ Next ☐ Second	Flat Rate Envelope ☐	
Date In Mo. Day Year	☐ 12 Noon ☐ 3 PM	Postage $	
Time In ☐ AM ☐ PM	Military ☐ 2nd Day ☐ 3rd Day	Return Receipt Fee	
Weight lbs. ozs.	Int'l Alpha Country Code	COD Fee	Insurance Fee
No Delivery ☐ Weekend ☐ Holiday	Acceptance Clerk Initials	Total Postage & Fees $	

DELIVERY (POSTAL USE ONLY)		
Delivery Attempt Mo. Day	Time ☐ AM ☐ PM	Employee Signature
Delivery Attempt Mo. Day	Time ☐ AM ☐ PM	Employee Signature
Delivery Date Mo. Day	Time ☐ AM ☐ PM	Employee Signature
Signature of Addressee or Agent X		
Name - Please Print X		

Addressee Copy

CUSTOMER USE ONLY

TO FILE A CLAIM FOR DAMAGE OR LOSS OF CONTENTS, YOU MUST PRESENT THE ARTICLE, CONTAINER, AND PACKAGING TO THE USPS FOR INSPECTION.

☐ **WAIVER OF SIGNATURE** (Domestic Only) **Additional merchandise insurance is void if waiver of signature is requested.** I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.

NO DELIVERY ☐ Weekend ☐ Holiday _____ Customer Signature

FROM: (PLEASE PRINT) PHONE ( ) _____

TO: (PLEASE PRINT) PHONE ( ) _____

HFA 305

FOR PICKUP OR TRACKING CALL 1-800-222-1811 **www.usps.gov** EMS

Label 11-B July 1997